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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,583	03/10/2004	Phil Langston	2005.63US01	4721
24113	7590	11/14/2006	EXAMINER	
PATTERSON, THUENTE, SKAAR & CHRISTENSEN, P.A. 4800 IDS CENTER 80 SOUTH 8TH STREET MINNEAPOLIS, MN 55402-2100			TOTH, KAREN E	
			ART UNIT	PAPER NUMBER
			3735	

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/797,583

Applicant(s)

LANGSTON, PHIL

Examiner

Karen E. Toth

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 and 13-23 is/are pending in the application.
- 4a) Of the above claim(s) 13-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Election/Restrictions***

2. Claims 13-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was confirmed **without** traverse in the reply filed on 2 August 2006.

#### ***Claim Rejections - 35 USC § 103***

3. Claims 1, 2, 6, 8-11, and 23 rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (US Patent 5480380) in view of Ladika (US Patent 4747840) and Bodicky (US Patent 4961731).

Regarding claim 1, Martin discloses a catheter comprising a manifold portion (element 24) comprising a first connector and a second connector (elements 36 and 38 – see figure 1); a coaxial dual lumen portion (element 22) comprising an inner lumen wall in communication with one connector and an outer lumen wall in communication with the other connector (see figure 8), where the distal end of the outer lumen wall contains a plurality of perforations (elements 48); and a single lumen portion with a generally straight portion (figure 1) in fluid communication with the inner lumen portion

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(see figure 6), where the lumen wall contains at least one side hole (element 50). Martin does not disclose the single lumen portion comprising a pigtail portion distal to a straight portion of the single lumen, or the inner lumen wall comprising braided extrusion reinforcement to accommodate high-pressure injections.

Ladika teaches a catheter comprising a single lumen portion with a straight section (element 26) and a pigtail portion (element 18) distal to the straight portion (see figure 1), in order to prevent the catheter from puncturing the patient's tissue (column 1, lines 60-66).

Bodicky teaches a cardiac catheter made of braided tubing (column 3, lines 8-20), in order to reinforce the device for high-pressure injections.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the device of Martin with a distal pigtail section, as taught by Ladika, in order to prevent the catheter from puncturing the patient's tissue, and formed the inner lumen with braided extrusion reinforcement tubing, as taught by Bodicky, in order to reinforce the device for high-pressure injections.

Regarding Claim 2, Martin further discloses the presence of a tapering portion (element 66) between the dual and single lumen sections of the device (see Figure 6).

Regarding Claim 6, Martin in view of Ladika and Bodicky discloses all the elements of the current invention, as applied to Claim 1 above, except for the inner lumen side holes being distributed in a spiral pattern over about 2 centimeters. Ladika further teaches that the single lumen portion comprises side holes that are distributed in a spiral array, in order to evenly distribute fluids. It would have been obvious to one of

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ordinary skill in the art at the time the invention was made to have made the catheter of Martin in view of Ladika and Bodicky, and distributed the inner lumen side holes in a spiral array, as taught by Ladika, in order to evenly distribute fluids.

Regarding Claim 8, Martin in view of Ladika and Bodicky discloses all the elements of the current invention, as applied to Claim 1 above, except for the single lumen portion further comprising a second straight portion joined to the first straight portion by a bend. Ladika further teaches that the single lumen portion of the catheter comprises a second straight portion (element 28) joined to the first straight portion (element 26) by a bend (element 22) (see Figure 1), in order to allow easier maneuvering inside a patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin in view of Ladika and Bodicky, and added the second straight portion to the single lumen section, as taught by Ladika, in order to allow easier maneuvering inside a patient.

Regarding Claim 9, Martin in view of Ladika and Bodicky discloses all the elements of the current invention, as applied to Claim 8 above, except for the angle between the first and second straight portions of the inner lumen being between about 130 and about 160 degrees. Ladika further teaches that the bend (element 22) between straight portions (elements 28 and 30) is between about 130 and about 160 degrees (column 5, lines 4-7), in order to properly maneuver within a patient's heart. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin in view of Ladika and Bodicky, and formed the bend

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between straight portions of the inner lumen to be between about 130 and about 160 degrees, as taught by Ladika, in order to properly maneuver within a patient's heart.

Regarding Claim 10, Martin in view of Ladika and Bodicky discloses all the elements of the current invention, as applied to Claim 9 above, except for the angle of the bend being about 145 degrees. Ladika further teaches that the angle of the bend is about 145 degrees (column 5, lines 4-7), in order to properly maneuver within a patient's heart. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin in view of Ladika and Bodicky, and formed the bend between straight portions of the inner lumen to be about 145 degrees, as taught by Ladika, in order to properly maneuver within a patient's heart.

Regarding claim 11, MPEP section 2113 states:

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)

Claims 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Ladika'840. Since the end result product meets the recited structure, the manner of making is not limiting.

Regarding claim 23, Bodicky further teaches that the chosen tubing is suitable for high-pressure injections at a pressure of at least about 1200 psi (column 3, lines 17-20, since 1000 psi is "about" 1200 psi).

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4. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Ladika and Bodicky as applied to claims 1, 2, 6, 8-11, and 23 above, and further in view of Miller (US Patent 5683640).

Regarding Claim 3, Martin in view of Ladika and Bodicky discloses all the elements of the current invention, as applied to Claim 1 above, except for the dual lumen portion having a diameter of greater than 6 French and the single lumen portion having a diameter less than or equal to 6 French. Miller discloses a dual-lumen catheter comprising a dual lumen portion with a diameter of greater than 6 French and a single lumen portion with a diameter of less than or equal to 6 French (column 4, lines 3-8), so that the device will properly fit within the vessels of a patient. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin in view of Ladika and Bodicky with the dimensions of Miller, so that the device will properly fit within the vessels of a patient.

Regarding Claim 4, Martin in view of Ladika and Bodicky discloses all the elements of the current invention, as applied to Claim 3 above, except for the dual lumen portion having a diameter of between about seven French and about 8 French. Miller further discloses that the dual lumen portion of the catheter has a diameter between about 7 and about 8 French (column 4, lines 3-5), so that the device properly fits within a patient's vessels. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin in view of Ladika and Bodicky with the dual lumen portion dimensions of Miller, so that the device properly fits within a patient's vessels.

Regarding Claim 5, Martin in view of Ladika and Bodicky discloses all the elements of the current invention, as applied to Claim 3 above, except for the single lumen portion having a diameter of about 5 French. Miller further discloses that the single-lumen portion of the catheter has a diameter of about 5 French (column 4, lines 6-7), so that it may easily maneuver within a patient's vessels. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin in view of Ladika and Bodicky with the single lumen portion dimensions of Miller, so that the device may easily maneuver within a patient's vessels.

5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martin in view of Ladika and Bodicky, as applied to claims 1, 2, 6, 8-11, and 23 above, and further in view of Duffy (US Patent 6048332).

Martin in view of Ladika and Bodicky discloses all the elements of the current invention, as applied to Claim 1 above, except for the outer lumen side holes being distributed spirally over about 4 centimeters of the lumen. Duffy teaches a catheter comprising an outer lumen (element 20) with spirally distributed holes (element 32) (see Figures 4 and 5b), wherein the length of the portion with the holes is about 4 centimeters (column 8, lines 42-45), in order to properly interact with the patient's fluids. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the catheter of Martin in view of Ladika and Bodicky with the spirally distributed holes of Duffy, in order for the device to properly interact with the patient's fluids.



***Response to Arguments***

6. Applicant's arguments filed 2 August 2006 have been fully considered but they are not persuasive.

Regarding applicant's arguments concerning product-by-process limitations, it is not necessary for the claim in question to be a manner of making a product. Rather, product-by-process limitations concern inventions that have the same form and function as the claimed invention, regardless of how the invention was formed. In this case, tubing formed by braided extrusion is a form of tubing characterized by its manner of manufacture. The original rejection merely states that a similar tubing not formed by braided extrusion (such as simply extruded tubing) would have a similar function and not be patentably different than applicant's claimed braided extrusion tubing.

Regarding Applicant's assertion that Ladika's "pliable thin walled" tubing (column 2, lines 27, 41-43) teaches away from tubing suitable for use in high pressure injections, the examiner respectfully disagrees, since the pliability and thickness of the tubing do not necessarily affect its strength. Similarly, applicant feels that Martin's "light thin walled inner lumen" also teaches away. Again, merely because the tubing is thin does not mean it is unsuitable for high pressure injections.

***Conclusion***


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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Ket

  
ROBERT L. NASSER  
PRIMARY EXAMINER